Aalto University
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# The effect of reference price regulation on pharmaceutical prices in Finland

Master's Thesis
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**Keywords** industrial organization, health economics, pharmaceuticals, reference pricing

# The effect of reference price regulation on pharmaceutical prices in Finland

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9th April 2019

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This thesis considers the impact of the Finnish reference pricing system on pharmaceutical wholesale prices. The policy, introduced in 2009, sets a maximum amount for the public reimbursement of pharmaceuticals assigned to the system. The reform was designed to improve the generic substitution practice that began in 2003. Using rich panel data for the years of 2006–2012, I apply the difference-in-differences method, exploiting the fact that some products never entered reference pricing. I find statistically significant evidence that prices fell by 5.9% in 2009 and 8.7% in 2010, after which the effect disappeared. However, concern with parallel price trends between the treatment and control groups prevents causal interpretation of the results.

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# Contents

# 1 Introduction

Reference pricing (RP) is a regulatory tool used to control prices and induce savings in reimbursement costs for the public sector. All Nordic countries have adopted RP in some form, directly or through generic substitution. It is also adopted as a regulatory tool in other European countries, most notably in large economies such as Germany, France and Italy (Panteli et al., 2016). Pharmaceutical care often constitutes a priority for patients, directly affecting the level of individual welfare. The burden of pharmaceutical expenditure is disproportionately heavily imposed on people in the lower socioeconomic class. Society as a whole must consider the affordability of pharmaceuticals. At the same time, the consumers' incentives have an impact on the public sector and the insurance companies, with pharmaceutical prices directly affecting their expenditures through cost-sharing structures. The motivation for my thesis builds on the welfare effects on patients and insurers.

This thesis concerns the effect of the 2009 Finnish policy reform on pharmaceutical prices. The reform stated that all interchangeable reimbursed medicines with generic competition must enter the reference pricing system (RPS). The main research goal of my thesis is to evaluate the price responses of pharmaceuticals subject to this RPS. I will also explore whether the effect differed for generic and branded pharmaceuticals. This relates to the generic competition paradox, proposed by Scherer (1993). The generic competition paradox describes the phenomenon where manufacturers of original pharmaceuticals raise prices when competition increases after patent expiration.

Existing empirical studies (Pavcnik, 2002; Brekke, Holmas, & Straume,

2011; Kaiser, Mendez, Rønde, & Ullrich, 2014) find that pharmaceutical prices fall after RP is adopted as a policy tool. The estimates have been significant in magnitude, varying between 10% and 30%. Most notably for this thesis, Koskinen (2014) found effects varying from 29.6% to 66.3% for antipsychotics in the Finnish RPS reform. The theoretical literature explains that pharmaceutical RP increases the price elasticity of demand above the reference price (Brekke, Königbauer, & Straume, 2007). However, previous findings have offered mixed evidence for the generic competition paradox. Most studies have focused on European or Nordic markets, where the role of the public sector is somewhat larger than, for instance, in the US. The main contribution of my thesis is to provide a difference-in-differences analysis using well-defined Finnish data.

This study uses product-level panel data on pharmaceutical prices between 2006 and 2012. For my empirical strategy, I apply the difference-in-differences method to estimate the effects of the RPS. I take advantage of the fact that not all products entered the RPS in 2009, most notably parallel-imported products. I find that that the prices in the treatment group fell by 5.9% and 8.7% in 2009 and 2010, respectively. The effects were not statistically significantly different for branded and generic pharmaceuticals. However, the main identifying assumption of parallel price trends between the control and treatment groups is not satisfied. My model empirically verifies that the price trends between the treatment and control group are not statistically significantly different for individual months before the RP reform. However, they are jointly significant. Thus, the results of my thesis should not be interpreted causally.

The structure of my thesis is as follows: Chapter 2 introduces the special

characteristics of the pharmaceutical market, together with the institutional setting in Finland and other Nordic countries. In Chapter 3, I present the most relevant economic literature on pharmaceutical RP. Chapters 4 and 5 cover the main empirical component of my thesis, presenting the data and the empirical strategy and results. In Chapter 6, I discuss the implications of my results for policy-makers and future research. Chapter 7 concludes the findings of my thesis.

# 2 Institutional and market characteristics

## 2.1 Market characteristics

In this section, I will introduce the Anatomical Therapeutic Chemical classification system (ATC) system that groups pharmaceuticals based on their therapeutic and chemical properties. The ATC system can be used to categorise the pharmaceutical market into smaller sub-markets in an economically meaningful way. It has significance for understanding the competition within the pharmaceutical market and in its applications in the empirical estimations. I will also provide a short introduction to drugs as goods. Thirdly, I will cover the role of government in cost-sharing in the pharmaceutical market.

The ATC system was created by the World Health Organization (WHO) and consists of five levels. It assigns a seven-digit code to each active ingredient in the system. The first digit determines the anatomical main group (1st level), the second and third digits are the therapeutic subgroup (2nd level), the fourth digit gives the pharmacological subgroup (3rd level), the fifth digit is the chemical subgroup (4th level), and the final two digits are the chemical substance (5th level). There are 14 main groups in the first level. The ATC system can define a sub-market based on the non-economic characteristics of a pharmaceutical.

To clarify, let us consider an example. A common pharmaceutical treatment for coronary artery disease (CAD) is cholesterol medication. Statins are a family of pharmaceuticals substances that lower the cholesterol levels. Two well-known statins are atorvastatin and simvastatin, introduced by the phar-

**Table 1:** ATC clasification of simvastatin

| Level | Description | Code | Definition |
|---|---|---|---|
| 1st | Anatomical main group | C | Cardiovascular system |
| 2nd | Therapeutic subgroup | C10 | Lipid modifying agents |
| 3rd | Pharmacological subgroup | C10A | Lipid modifying agents, plain |
| 4th | Chemical subgroup | C10AA | HMG-CoA reductase inhibitors |
| 5th | Chemical substance | C10AA01 | Simvastatin |

This table presents the five ATC levels for the active ingredient simvastatin.

maceutical manufacturers Pfizer (or Warner–Lambert at the time) and Merck. The ATC code for atorvastatin is C10AA05 and the code for simvastatin is C10AA01. The codes differ only in their final two digits. The first 'C' stands for cardiovascular system, 'C10' for lipid modifying agents, 'C10A' denotes plain lipid modifying agents, 'C10AA' refers to HMG-CoA reductase inhibitors, and 'C10AA01' and 'C10AA05' are thus simvastatin and atorvastatin (WHO Collaborating Centre for Drug Statistics Methodology, 2018). Table 1 provides the classification for simvastatin.

Most pharmaceutical markets are both horizontally and vertically differentiated, which is best explained in terms of therapeutic and generic competition. The ATC system can be used to determine therapeutic competition, which describes competition between different chemical substances used for treatment of the same disease. In our example, simvastatin and atorvastatin belong to the same ATC4 group, making them therapeutic competitors. It is possible to consider a narrower market as the market for statins (ATC4) or a broader market as the market for lipid modifying agents (ATC2). In the traditional sense, therapeutic competition corresponds to the horizontal axis

of the product space.

Generic competition describes competition between firms manufacturing the same chemical substance. Even though the products are fully homogeneous in respect to their chemical and therapeutic properties, the perceived differences between the manufacturers vertically differentiate the products in the eyes of the consumers (Brekke et al., 2007). To continue the previous example, the respective retail names of atorvastatin and simvastatin from Pfizer and Merck are Lipitor and Zocor. Both Lipitor and Zocor received patents and entered the market in the 1990s. The patent for Lipitor expired in 2011 and the patent for Zocor in 2006. After patent expiration, competing firms began to manufacture copies of the drugs, thus creating generic competition. As the original products, Lipitor and Zocor are the branded products. The trade names of generic manufacturers usually only include the name of the active ingredient and the manufacturer, such as 'Simvastatin Actavis', which is a generic competitor to Zocor, manufactured by Acativis Generics.

Branded products often have higher prices than their generic counterparts. For homogeneous products, one would expect marginal cost pricing in a Bertrand manner after patent expiration. General economic theory provides multiple explanations for the existence of persistent brand preferences. To name a few examples, Bronnenberg and Dubé (2017) list learning over lifetime, switching costs, and information effects through search costs or consumer knowledge and expertise. The latter is further studied by Bronnenberg, Dubé, Gentzkow, and Shapiro (2015), who find that consumers with pharmacy education are more likely to buy generic pharmaceuticals.

Pharmaceutical research and development have high costs (Chan, Lakonishok, & Sougiannis, 2001) and pharmaceutical products often enjoy strong

intellectual property rights to compensate for this. A patent period granted to an original manufacturer gives monopoly rights for a fixed period time. However, after patent expiration, other manufacturers may enter the market with their own copies of the original product.

Government regulation of the pharmaceutical sector is wide-ranging. First, some pharmaceuticals require a prescription from a licensed physician. These prescription drugs are often denoted by the symbol 'Rx'. Products that do not require a prescription are known as over-the-counter pharmaceuticals (OTC). Secondly, cost-sharing, or reimbursement, of pharmaceutical prices, either through public health care or health insurance, is common. This means that the cost of the pharmaceutical is shared between the patient and the insurer, public or private. The price paid by the patient is often a percentage share of the list price (out-of-pocket payment), but it can include a small fixed fee, or 'co-payment'. I provide a brief introduction to the Finnish reimbursement system in the next sub-chapter.

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2018) provides the following definition of a pharmaceutical RPS:

> Reference Price System - A reimbursement policy in which identical medicines (ATC 5 level) or similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments (e.g. prescription fees, or percentage co-payment rates).

There are two distinct designs or systems for pharmaceutical RP: external

price referencing (EPR) and internal price referencing (EPR). They can also be expressed as external reference pricing (ERP) and internal reference pricing (IRP). The definitions of these from the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2018) are as follows:

> External price referencing - The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
>
> Internal price referencing - The practice of using the price(s) of identical medicines (ATC 5 level) or similar products (ATC 4 level) or even with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.

The key difference between ERP and IRP systems is the calculation pool of the reference price. In an ERP system, the policy-maker considers foreign prices, and in an IRP system, domestic prices. The next two sub-chapters present the characteristics of different RP systems in Finland, Sweden, Denmark, and Norway. I use the definitions of ERP and IRP to define a reference price (maximum reimbursement) for a product, unless specified otherwise. I will discuss the differences between the two systems in Chapter 3.

## 2.2 Finland

### 2.2.1 Institutional background

Finland provides universal health care to all its citizens. Most health care expenditure is covered by the public sector, which is financed through taxes. Statistics for 2016 indicate that the public sector covered approximately 74% of all costs related to health care (THL, 2018). The remaining share was paid primarily by households. In the pharmaceutical market, the Finnish government reimburses vital medicines sold in the retail sector for ambulatory care. Finnish hospitals also issue pharmaceuticals free of charge to their patients as part of their primary or special care. In 2017, the public sector covered more than 60% of all pharmaceutical expenditure (Kela and Fimea, 2018).

Due to the dangers of illicit use of pharmaceuticals and the strong financial interest to the public sector, the Finnish pharmaceutical market is heavily regulated. The Finnish Medicines Act regulates market authorisation and the sale of pharmaceuticals in the retail sector. The Finnish Health Insurance Act regulates government reimbursement. Finnish Medicines Agency (Fimea) is responsible for market authorisation procedures and determines which medicines are substitutable. Finnish Social Insurance Institution (Kela) is responsible for reimbursements, though the decisions are made by the Finnish Pharmaceuticals Pricing Board (Hila), which operates under the Ministry of Social Affairs and Health. Hila determines the reimbursement for pharmaceuticals and sets price caps for reimbursed medicines at the wholesale level. Since the reform of 2009, Hila has also issued decisions regarding the new RPS. In addition, the Finnish government has issued further expanding legislation in the form

of decrees, such as the Medicines Decree and Pharmaceutical Prices Decree.

There are four distinct processes through which a product can receive market authorisation for sale in the Finnish market (Fimea, 2018). Firstly, the authorisation can be applied at the European level by the European Medicines Agency (EMA) through a centralised procedure. An authorisation granted by EMA is valid in all member states, as well as in Iceland, Liechtenstein, and Norway. There are two other processes that include cooperation between the member states but are not governed by EMA. In the decentralised process, a company simultaneously applies for market authorisation from more than one member state through the national authorities, on the condition that the product has no market authorisation in any of the member states. The decentralised process is directed by one of the member states and other national authorities provide assistance in the process. The mutual recognition process applies when a company applies for market authorisation for a product that has been approved in at least one member state. The centralised, decentralized, and mutual-recognition processes are regulated in the directives passed by the European Union (EU). Finally, a company can apply for market authorisation directly from Fimea through the national process, which is regulated by the Medicines Act and Medicines Decree.

As of 2018, the processing times for market authorisation applications are 210 days for the centralised, decentralized, and national processes. The maximum time limit for the mutual recognition process is 90 days, as the product is already sold in at least one member state. A crucial distinction in the market authorisation processes also arises from the patent status of the product. In the case of new generic products, the applicant is freed from the requirement to provide pre-clinical and clinical trials results if the original product has had

market authorisation for at least eight years and has identical properties to the new product. However, the Finnish Medicines Act dictates that the market authorisation of a generic product can come into force not earlier than 10 years after the original product received its authorisation, irrespective of the original product's patent expiration.

There are only two major wholesale operators in the country – Tamro and Oriola – making the wholesale market rather centralised. On the other hand, the retail sector in Finland is decentralised due to government regulation. The Finnish Medicines Act determines that a pharmacy operating license can only be issued to an individual person. To receive an operating license, the applicant must hold a master's degree in pharmacology and must not have been declared bankrupt or be under legal guardianship or legally incompetent. The number of pharmacy licences is regulated and each licence is restricted to a geographically distinct area. Fimea determines a sufficient number of pharmacies for the country and issues the operating licences accordingly. Pharmacists operate at personal risk and all revenue is their own personal income. Pharmacy retail prices are directly regulated by the government and depend on the wholesale price of the product. Retail prices are uniform across all pharmacies. For prescription medicines, retail price is incremented by a fixed dispensing fee. All pharmaceuticals are subject to value added tax (VAT). In contrast to other Nordic countries, Finland restricts the sales of OTC products to pharmacies.

Finland has three levels of public reimbursement: the basic reimbursement level, the lower special reimbursement level, and the higher special reimbursement level. As of 2018, the levels are 40%, 65%, and 100%, respectively. The reimbursement levels are time-variant. This includes the percentage level for the government reimbursement, as well as the reimbursement status at the

product level. In contrast to the first two levels, the higher special reimbursement level also has a co-payment of 4.50 euros per prescription. Total patient expenses are capped at 610 euros, after which the government reimburses any remaining cost, with a 2.50 euro co-payment. This is called the 'additional reimbursement' and the cap is tied by law to a price index. Since 2016, the government reimbursement has been limited so that it begins after the patients' expenses exceed 50 euros.

Entry of pharmaceuticals into the reimbursement system is regulated by the Finnish Health Insurance Act and governed by Hila. The reimbursement of the product is tied to its wholesale price and the manufacturer is required to provide evidence of a reasonable wholesale price. This determines the maximum reimbursable price for the product. In practice, the reasonable wholesale price is the price cap for all reimbursed products. The reimbursement decision must be made within 180 days, or 90 days if the applicant applies for an increase with respect to a previously decided wholesale price. Hila can increase the decision time by a maximum of 60 days, but only if it receives several applications at the same time. Hila can issue restrictions on the reimbursement based on the type of disease or prescription, known as 'conditional reimbursement'. As of 2018, a reimbursement decision and reasonable wholesale price approved by Hila remain in effect for a maximum of three or five years, depending on whether the product is a new substance. However, the company may apply for a higher wholesale price if it is able to show that, for instance, manufacturing costs have permanently risen.

### 2.2.2 Reforms in the Finnish pharmaceutical market

The changes in Finnish legislation concerning pharmaceuticals and pharmaceutical benefits over the last 20 years comprise two major reforms and several smaller revisions. The largest reforms were the 2003 generic substitution reform and the 2009 RPS reform, the latter of which is the policy of interest in my thesis. The smaller reforms include changes in the reimbursement system and pharmacy mark-ups. In this subsection, I present the most important of the reforms.

Generic substitution became mandatory in Finland on 1 April 2003.[1] The legislation requires pharmacies to substitute a prescription product for an alternative interchangeable product that is either the cheapest or only slightly more expensive than the cheapest (this difference being defined as the 'price corridor'). The price corridor was set to two euros for products costing less than 40 euros and to three euros for those costing 40 euros or more. In Finland, physicians can prescribe medicines by writing the name of either the product or the active ingredient(s). If they choose the latter, this is known as 'generic prescribing'. It is important to note that OTC products can be prescribed by physicians and are thus affected by the legislation, although this is rare.

Fimea categorises interchangeable pharmaceuticals on the basis of their active ingredient, strength, and pack size. These characteristics constitute the substitution groups. The cheapest price is determined quarterly for each substitution group from the pharmaceutical retail prices. The 2003 reform affected all pharmaceuticals prescribed by a physician, regardless of their reimburse-

[1] Finnish Medicines Act, 80/2003.

ment status. The legislation on generic substitution retains the patient's right to refuse a substitution without affecting reimbursement level. It also allows physicians to forbid substitution on the basis of pharmaceutical safety. Generic substitutions offer only small incentives to patients, as they would always receive the same level of reimbursement. For fully reimbursed pharmaceuticals, the incentives for substitution were almost non-existent.

Before generic substitution was mandatory, voluntary generic substitution and generic prescriptions were possible in Finland.[2] Between 1993 and 1995, physicians could allow generic substitutions by actively specifying that such substitutions were possible. Between 1996 and 2002, this was replaced by generic prescribing. This meant that physicians must use the name of the active ingredient, rather than of the product, to enable the generic substitution. In both cases, pharmacies were required to dispense the cheapest available product, or another only insignificantly more expensive. However, previous research found the results of these policies to be small (Martikainen, Rajaniemi, & Klaukka, 1999). In contrast to mandatory generic substitution from 2003, the previous systems were dependent on physicians and not pharmacies, with the likely inconvenience to physicians leading to only insignificant numbers of voluntary substitutions being made.

Generic substitution was supplemented by the RPS reform in 2009.[3] This reform is the focus of the research question of my thesis. The objective of the RPS was to increase patients' incentives to commit to generic substitution. In its simplest form, the RPS requires the patient to pay the price

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2 Ministry of Social Affairs and Health, 1993, 1995.

3 Finnish Health Insurance Act, 802/2008.

differential of the prescribed product and the substitutable product offered if the patient refuses the substitution. More precisely, public reimbursement was capped within the substitution groups – now denoted as 'reference price groups'. If pharmaceutical substitution is forbidden by the prescribing physician, the patient receives the normal reimbursement based on the retail price of the product.

Between 2009 and 2017, the reference price was calculated as the lowest retail price (including the service fee) within the reference price group, and incremented with 1.50 euros or two euros, if the price was 40 euros or more (the price corridor). The change in the price corridor was also applied to normal generic substitution. The reference price is the maximum reimbursed price for all products within the reference price group. If the price of the product was less than the reference price (within the price corridor), the reimbursement was calculated based on the actual retail price. The Pharmaceuticals Pricing Board was tasked with determining the quarterly reference prices based on the prices of the first monthly pricing period of each quarter. The reform took effect on 1 April 2009.

It is crucial to note that the legislation is strict in defining the fundamental aspects of the establishment of reference price groups. All substitutable and reimbursed products that have one or more generic competitors are assigned to the system. Thus, almost all reimbursed products under generic competition are assigned to reference price groups.

However, there are two important remarks to be made. First, the RPS reform initially left parallel-imported and parallel-distributed products out of the RPS. A parallel import is a product imported to the market by a third-party distributor without a licence from the initial intellectual property holder.

This exploits the price arbitrage of products between different countries, such as Finland and Estonia. Parallel imports are protected by law in the European single market. Parallel distributed products are parallel imports whose original product received its market authorisation through the centralised procedure. Before 2017, parallel imports and distributed products could not constitute a reference price group if the substitution group did not include a competing generic product in the market. This characteristic is at the core of my analysis in Chapter 5. Secondly, the reference price was set quarterly; but within the quarters, the companies could price biweekly.[4] Hypothetically, this could mean clustering prices to the reference price for products during each RP period.

Since 2016, the Finnish Medicines Act has required pharmacies to inform customers about the product with the lowest actual retail price within a substitution or reference price group.[5] This means that the pharmacy must inform the customers which product in the price corridor is the cheapest. This change was important in the context that pharmacists have an incentive to offer substitution for products in the upper-end of the price corridor.

The RPS was modified in 2017.[6] This change in legislation expanded RP to parallel-imported and parallel-distributed products, removed the 40 euro threshold in the calculation of the price corridor, and defined the accepted price difference to 0.50 euros (the latter two changes also applying to generic substitution).

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4 The biweekly pricing process is government-regulated. Prices are updated on the 1st and 15th day of each month.

5 Finnish Medicines Act, 253/2015.

6 Finnish Health Insurance Act, 1100/2016.

On 1 January 2016, the Finnish Health Insurance Act declared that a new generic product could be accepted into the reimbursement system only if its reasonable wholesale price was no more than 50% of the price of the original product.[7] However, in practice, this rule had been in application since 1 July 2006, when Hila delegated to its director the authority to accept new generic products into the system if the prices were no more than 60% of the original. It is possible that this percentage rule was applied in practice by the whole board even prior to this. At the same time, the government also introduced a restriction on the reimbursement of pharmaceuticals, limiting payments to begin only after 50 euros of a patient's pharmaceutical expenses.[8]

Finally, there have been minor changes to public reimbursement percentages over the past 20 years. In the context of this thesis, the levels remained the same for the period of 2006 to 2013. Four other government policies are also noted here. First, the Finnish parliament has twice issued mandatory price cuts (5 pp.) to the wholesale prices of all reimbursable pharmaceuticals. These two cuts came into force on 1 January 2006 and 1 February 2013. A third cut was issued for products in the RPS with higher wholesale prices than their generic competitors. The new price was set at the level of the highest generic wholesale price.[9] In practice, the price cuts were mandatory because the alternative offered was removal of the product from the reimbursement system. Secondly, and finally, the government set the new pharmacy mark-ups in 2014, replacing the previous regulation from 2003.[10] I will discuss the

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7 Finnish Health Insurance Act, 252/2015.

8 Finnish Health Insurance Act, 1656/2015.

9 Finnish Health Insurance Act, 885/2005, 622/2012, 252/2015.

10 Finnish Pharmacy Mark-up Decree, 713/2013.

implications of the reforms in respect to my data period in more detail in Chapter 4.2.

## 2.3 Other Nordic countries

RP and generic substitution are common policy tools in all Nordic countries. The Danish RPS began in 1993, although generic substitution only became mandatory in 1997.[11] The reference price was initially based on IRP and replaced by ERP during 2000 and 2005.[12] In the ERP system, the reference price was determined as the lowest average price within a substitution group in the EEA country basket. In the first IRP system, the reference price was set as the average price of the two least expensive products within a substitution group. In the current system, the reference price is based on the generic substitution: more precisely, the reference price is calculated as the lowest price within a substitution group at the national level. Since pharmaceutical prices are allowed to change every 14 days, the reference price in Denmark can change twice a month.

Sweden used internal IRP during 1993 and 2002. The system capped the maximum reimbursement at 110% of the price of the cheapest product within an reference price group. However, the system did not include mandatory generic substitution. The latter replaced the RPS on 1 October 2002.[13] In the new system, the maximum reimbursement price was determined by the cheapest

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[11] Danish Public Health Insurance Act, 1138 of 22/12/1993; Danish Prescription Degree, 308 of 06/05/1997.

[12] Danish Public Health Insurance Act, 1031 of 23/11/2000, 1431 of 22/12/2004.

[13] Swedish Act on Pharmaceutical Benefits, 2002:160.

price within a substitution group at the pharmacy level. Interpretation of the regulation changed in 2009, with the cheapest price of a substitution group then calculated at the national level. In practice, pharmaceutical manufacturers issue monthly prices (bids) and the winner in the substitution group is the product with the lowest price, denoted as the product of the month for each substitution group. Generic substitution in pharmacies is required for those products, but the government can declare the same status for secondary products if the stock of the initial winner is exhausted. Although its system resembles that of Denmark, in Sweden, the market authorisation holder of a winning bid can expect to receive all demand for substitutions. If a patient requests any other generic product, there is no reimbursement at all.

Norway has used ERP since the year 2000.[14] The maximum reimbursement price is calculated as the average of the three lowest prices in a country basket comprising EEA countries. If there are fewer than three prices available, the reference price is the average of those. ERP replaced the internal RPS from 1993. A crucial concept in the Norwegian ERP is that generic products have the same price cap as the original products.

Generic substitution became possible in Norway in 2001.[15] Pharmacies are required to offer price information if generic competition exists, but substitution is not mandatory. If a patient refuses the substitution of a reimbursed product, the patient is required to pay the price difference between the two. During 2003–2005, an internal RPS called 'index pricing', or 'index-RP', was in place for six pharmaceutical substances to strengthen generic substitution.[16]

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[14] Norwegian Decree on Medicinal Products, 1999-12-22-1559.

[15] Norwegian Pharmacies Act, 2000-06-02-39.

[16] Norwegian Decree on Medicinal Products, 2003-02-25-232.

The index price was calculated quarterly and it was based on the (market share) weighted average price within substitution groups. The index price constituted the maximum reimbursement price. Patients were required to pay the difference in price between two products if they refused a substitution. However, pharmacies were able to receive the difference between the index price and the actual retail price if they dispensed a product cheaper than the index price. This increased the pharmacies' incentive to offer generic substitution because of the higher mark-up. A seventh active ingredient was added in 2004, but the system was discontinued in 2005.

Norway replaced index pricing with a stepped-price model in 2005.[17] In the new system, the government gradually reduces the maximum reimbursement price after generic competition begins. The step price is the maximum reimbursement price and thus technically resembles RP. Pharmacies are required to stock at least one product at the step price, and they receive the margin between the step price and the actual retail price.

The examples from other Nordic countries show that there are both differences and similarities between different RPSs. For example, the Norwegian ERP closely resembles the Finnish system, where Hila decides on a reasonable wholesale price for a product. However, although Hila is required to consider the price level of the product in other European countries, no direct pricing rule is applied, as in Norway. Thus, it is used more as a benchmark rather than a price control tool. In Denmark, the wholesale pricing is free from regulation and the RP (external or internal) constitutes the main price control tool. Furthermore, a generic substitution system can create a de facto internal RPS, as

[17] Norwegian Decree on Medicinal Products, 2004-12-17-1712.

in Denmark and Sweden. In comparison to the Finnish RPS, the other Nordic regulatory models do not include a price corridor and have shorter time periods for the reference price. Theoretically, firms in Finland have smaller incentives to set the lowest prices, since firms are able to adjust their prices to the reference price (the upper limit of the price corridor) and remain there for the quarter. This can cause inertia in market competition.

# 3 Literature review

## 3.1 Theoretical background

### 3.1.1 Horizontal and vertical differentiation models

Theoretical research on pharmaceutical RP has received less attention than the empirical work. However, there are some notable exceptions. Brekke et al. (2007) apply the famous Hotelling's location model with horizontal and vertical dimensions for product differentiation. In the context of the pharmaceutical market, the horizontal dimension is determined by therapeutic competition, while generic competition represents vertical differentiation. The model considers both generic and therapeutic RP and compares them to a situation without any RP. The researchers included three firms and two pharmaceutical substances: two original manufacturers and one generic competitor. The two pharmaceutical substances are therapeutic competitors, but one of the original manufacturers has lost its patent protection and thus received a generic competitor.

In the absence of RP, the model results in a weaker version of the famous generic competition paradox proposed by Scherer (1993). In the paradox, generic entry leads to price increases from the original manufacturer, counterintuitively making generic and branded products strategic complements. In the model of Brekke et al. (2007), a weaker version of the paradox emerges. In this case, the original manufacturer lowers its prices, but maintains them at a higher level than the generic firm. In both cases, the branded firm targets the least price sensitive market segment. The market is separated as the generic

manufacturer captures the most price sensitive market. When there is no RP, the original manufacturer maintains the highest price level, followed by its (branded) therapeutic competitor and lastly the generic firm. Brekke et al. (2007) demonstrate that this kind of market separation is the only situation in which the generic firm can survive the competition.

Introduction of generic RP leads to price decreases as the competition increases between the generic manufacturer and the branded off-patent manufacturer. This time, however, the branded firm without generic competition has the highest price. Furthermore, the price levels are lowest in the case of therapeutic RP. Since the branded on-patent manufacturer is included in the RPS, therapeutic RP induces even more competition in the market. In their model, the authors define the reference price as the lowest price.

RP is usually paired with product substitution for interchangeable products. In practice, however, there are very few therapeutic RPSs in use. This contradicts the previous theoretical model that presents therapeutic RP as the most efficient of the alternatives. A likely explanation is that therapeutic substitution is more dangerous to patients. Even though some pharmaceuticals can be safely substituted even between different molecules, this cannot be guaranteed for all products and patients. Governments are likely to be wary of the uncertain consequences and thus implement policies based on generic RP.

A similar study by Miraldo (2009) also applies Hotelling's location model with both horizontal and vertical differentiation. Unlike Brekke et al. (2007), Miraldo (2009) does not assume that consumers have unit demand and full market coverage. Instead, her model allows for consumers to opt out of buying. Unfortunately, the analysis compares RP to a base situation without government reimbursement. Since, by definition, public reimbursement is part of the

pharmaceutical RPS, the results of the model do not allow the separate interpretation of reimbursement and RP. In the case of government reimbursement, the model finds consumers to become less price sensitive as they do not carry the entire cost of the pharmaceutical product. This contrasts with the model of Brekke et al. (2007), which allows a proper evaluation of a RPS reform in which government reimbursement already exists.

The contribution of Miraldo (2009) to the economic literature concerns the effect of information on firms' pricing strategies. The model considers a scenario in which the reference price of a period is based on the price level of the previous period. Thus, manufacturers are made aware of the impact of their pricing decisions on the reference price in future periods. Miraldo (2009) labels this 'the anticipation effect'. The model indicates that the anticipation effect provides firms with a positive incentive to pursue a higher future reference price by raising prices today. This, of course, leads to higher price levels. These incentives make tacit collusion between firms easier, which also leads to higher prices. Finally, the anticipation effect has two profound implications. Firstly, if firms are able to foresee the policy implementation, they can increase the prices before RP takes effect. Secondly, if the reference price is calculated based on historical prices, the firms understand this endogenous connection between the pricing periods.

### 3.1.2 Exogenous and endogenous reference pricing

Brekke et al. (2011) define two types of RP based on the different calculation methods for the pharmaceutical reference price. The reference price is said to be to be endogenous if the calculation method internalises the firms' pricing

decisions in the market. However, the reference price is defined as exogenous if the firms' price setting does not affect the reference price. The two definitions are useful for describing the two most commonly applied regulatory approaches. ERP is a method in which the reference price is calculated from the price levels in non-domestic markets. For instance, the Danish RPS between 2000 and 2005 calculated the reference price as an average of prices in comparative countries, such as other Nordic countries and other EEA member states. ERP is fully exogenous, as the reference price is defined as a function of the prices abroad and the cross-price elasticities are likely to be small between countries. In IRP, the reference price is calculated from domestic prices. This is endogenous, as the firms internalise the effect of their prices on future reference price levels.

The effects of the two systems can be vastly different. Brekke et al. (2011) show that exogenous RP can cause clustering of prices near the reference price. Products that were initially prized higher than the reference price (branded products) face pressure to lower their prices as a result of increased consumer price elasticity. However, products that fall below the reference price (generic products) face an incentive to raise prices. Since the reference price is exogenous, the changes in domestic prices do not affect the level of the reference price. In the case of endogenous RP, the system induces more competition between products, as the firms internalise the externality at the reference price level. The theoretical model of Brekke et al. (2011) indicates that, under endogenous RP, prices are lower for both branded and generic manufacturers.

The Finnish RPS represents IRP, as the quarterly reference price is endogenously determined by competition within reference price groups. Theoretically, I can expect the RPS reform to have induced price decreases for both

branded and generic pharmaceuticals. If the price decreases are smaller for generic products, the results represent the weaker version of the generic competition paradox. In all specifications of RP, the idea is the same: to make consumer demand more elastic above the reference price.

## 3.2 Past empirical results

The Swedish RPS reform of 1993 set the maximum reimbursement level at 110% of the price of the cheapest generic alternative. Aronsson, Bergman, and Rudholm (2001) estimated the effects of the regime change on market shares and relative prices for 12 pharmaceutical molecules. In their paper, Aronsson et al. (2001) used quarterly price and sales data from the Swedish Medicines agency for the years 1972-1996. The data include the prices of the original product and the weighted average prices of the generic competitors.

Because the model of Aronsson et al. (2001) was a before-and-after design without a control group, it is likely that the estimations are largely inaccurate and biased. Aronsson et al. (2001) found negative and statistically significant effects for the market shares of three pharmaceutical substances. However, the aggregated effect on market shares was not statistically significant. The authors point to the price responses of branded manufacturers to explain this. They found that that the average effect on relative prices (in relation to generic prices and to the initial branded price in period 0) was -0.47 and -0.48, both of which were statistically significant. The interpretation is that branded manufacturers reacted by lowering their prices, which contradicts the generic competition paradox. However, the estimation of a relative price does not have an unambiguous economic interpretation and thus the magnitude of the

results remains unclear.

It is noteworthy that the Swedish reform of 1993 was fundamentally different to the modern RPSs. Importantly, the system placed a cap on public reimbursement, but it did not include generic substitution. As discussed in Chapter 2, Sweden had mandatory generic substitution only after 2002. Thus, the effects of the 1993 reform were decided by the behaviour of the prescribing physicians. The RPS was in effect until 2002, when it was replaced by generic substitution.[18]

Bergman and Rudholm (2003) take a more precise approach to understanding the Swedish reform of 1993. Their data concern price and sales for 1972-1996 for 18 pharmaceutical substances, six of which did not have generic competition and were not subject to the reform, thus forming the control group. However, all the products had expired patents by 1990 and thus the substances in the control group were at least under threat from generic competition. The authors estimate that the reform lowered the prices of pharmaceuticals subject to RP by 16-21%. The researchers identify no effects on the prices of products that faced potential competition, which has strong implications for the definition of the control group in my empirical strategy. Both Aronsson et al. (2001) and Bergman and Rudholm (2003) include estimates of the number of generic competitors. This control variable is likely to be endogenous and it is also present in the model of Brekke et al. (2011). I will discuss this further in Chapter 5.

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[18] In reality, it can be argued that Swedish generic substitution between 2002 and 2009 was also an internal RPS because it limited public reimbursement to the cheapest price of a substitutable product at the pharmacy level.

Pavcnik (2002) considers the effect of introducing RP into Germany in the early 1990s. In the German RPS, the Federal Commission of Physicians and the Statutory Health Insurance Committee ('the Federal Joint Committee' since 2004) capped public reimbursement to a reference price calculated for therapeutic groups, adjusted by package size and pharmaceutical strength. Importantly, the reference price is usually set between the price level of the branded product and the generic substitutes. The German system was implemented gradually, beginning in 1989. Pavcnik (2002) uses quarterly package level data from IMS Health. The data has both volume and sales value information. However, Pavcnik (2002) aggregates the data to the product name level and converts the prices to the daily doses sold.

The core estimations of Pavcnik (2002) concern oral antidiabetics. Depending on the model, the resulting price decreases varied between 11.2% and 12.3% for the generic products and 26.0% and 21.7% for the branded pharmaceuticals. Thus, Pavcnik (2002) found no generic competition paradox in her results. The setting of the German reform allowed Pavcnik (2002) to apply a control group in her estimations, as not all oral antidiabetics were assigned to an reference price group at the start of the policy. The results of this study constitute the first empirical evidence that IRP lowers pharmaceutical prices especially for branded products.

The German RPS was enhanced in 2007 by the introduction of co-payment exemption levels. Previously, all publicly reimbursed pharmaceuticals imposed a co-payment on the patient, but this was changed under the new system. The regulation exempted products from patient co-payments if their price was below a certain level determined by the regulator for each reference price group. Herr and Suppliet (2017) explore the effects of the new policy on prices by

applying the difference-in-differences method as an empirical strategy. The authors use quarterly product and package level pricing data from the German Institute for Medical Documentation and Information. They found that prices fell by 5.0–6.2% for generic products and rose by 3.3–4.2% for branded products, thus satisfying the generic competition paradox. The reform did not alter the reference price itself; rather, it created a threshold below which the price of the product would be fully reimbursed.

Kaiser et al. (2014) evaluated the 2005 Danish transition from external to internal RP. Prior to the reform, and since 2000, Denmark had used ERP. Under the old system, the reference price was calculated within a group of substitutable products as the average price within a European country basket. From 1 April 2005, the reference price was calculated as the lowest domestic price in a substitution group. Thus, it somewhat resembles the Swedish system adopted in 2009.

Kaiser et al. (2014) use data on volume and price of statins between 2003 and 2007, with an empirical strategy that is somewhat unique in the context of empirical literature on pharmaceutical RP. The researchers first model the traditional BLP-type (Berry, Levinsohn, & Pakes, 1995) supply and demand estimation for statins over all time periods. They then conduct a pricing equation for each period, through which they build a contrafactual of the price path without the internal RP reform. They verify the weaker version of the generic competition paradox in Denmark, where prices of branded pharmaceuticals were seen to decrease by 2%, while generic prices saw a decrease of 45%. In the context of the results in the existing empirical literature, the magnitude of this difference is somewhat surprising.

In addition to the theoretical model of endogenous and exogenous RP,

Brekke et al. (2011) studied the effects of the 2003–2005 Norwegian index pricing. Their results form the basis of this thesis. As discussed in the previous chapter, Norway used index RP for a small sample of off-patent pharmaceutical substances between 2003 and the end of 2005. Since most products remained within the old price cap regulation, the reform can be described as a quasi-natural-experiment. Using a rich dataset of product prices and sales volumes, the authors applied the difference-in-differences method to estimate the effect of the reform on prices and generic market shares. Brekke et al. (2011) aggregated their data on 24 active ingredients or ATC5 groups, seven of which are included in the index pricing system. They also aggregated the data by brand status to separate the effects of generics and branded pharmaceuticals. They found that, on average, prices fell by 33% for branded pharmaceuticals and 22% for generic products. They also found that the reform decreased the market share of branded pharmaceuticals by almost 15%.

However, it is crucial to note that the control group in the Brekke et al. (2011) study constituted off-patent pharmaceuticals subject to generic substitution. Thus, as explained in the previous chapter, in practice, these products could carry additional costs for a patient who refused the substitution. Thus, Brekke et al. (2011) studied the effects of a change in pharmacies' incentives rather than the RPS itself.

The Brekke et al. (2011) study was a follow-up to a previous empirical study by Brekke, Grasdal, and Holmås (2009). In the latter paper, the authors found that pharmaceutical prices fell by approximately 7% for generic pharmaceuticals and 18% for branded pharmaceuticals. These estimates are smaller than those in the 2011 follow-up, which is likely due to Brekke et al. (2011) excluding on-patent products from the data. Brekke et al. (2011) also

extended their analysis by including estimations of branded and generic market shares. The contribution of this paper concerns the effect of the policy on therapeutic competitors (in terms of ATC2 groups), with the authors able to verify a negative cross-price effect on competitors. However, the definition of therapeutic competition might prove too broad. Filtering competitors at ATC2 level defines the control group as consisting of inherently different products, which stretches the assumption of parallel time trends.

The empirical literature provides mixed evidence for the possibility of the generic competition paradox. The results from Pavcnik (2002) and Brekke et al. (2011) indicate that the price decreases are larger for branded pharmaceuticals than for generics. On the other hand, the more recent study by Kaiser et al. (2014) seems to satisfy the weaker version of the paradox. It is possible that the results are dependent on the regulatory environment before the launch of the RPS, and proving the existence of the phenomenon is not feasible. In this sense, the price reactions for branded or generic products might have little external validity for non-domestic pharmaceutical markets.

Most notably for this thesis, Koskinen (2014) studied the effect of the Finnish RPS reform on the prices of four antipsychotic substances. The empirical strategy is based on segmented linear regression. In other words, the study used a regression where the pre-treatment and post-treatment period were assigned different constant terms and monthly time trends. Each substance was regressed independently. The design is to capture the permanent effects of the policy by the difference in the constants and the change in trends by the difference in the coefficients of the time trends. The dependent variable was the mean cost of daily medication.

The empirical strategy used by Koskinen (2014) identified negative effects

on prices. Prices fell permanently by between 29.9% and 66.3%. The changes in the time trends were smaller in magnitude, but nonetheless negative. However, the findings suffer from weak internal validity. As the authors did not use a control group, a causal interpretation of the results is questionable. In addition, although the authors take autocorrelation into account in their estimations, they do not consider the possibility of non-stationarity in the time series data used in the estimations. The empirical strategy of this thesis allows a more robust estimation of the effects of the Finnish RPS reform.

A meta-analysis by Acosta et al. (2014) reviewed a total of 18 studies from 1983–2011. The authors conclude that, 'The quality of evidence was low for all of the outcomes reported in the included studies for reference pricing' (Acosta et al., 2014). The risk of bias was highest for the assumptions in which the interventions studied were independent of other changes.

Thus, an unfortunate characteristic of past empirical research is low quality. The use of possibly endogenous control variables (such as number of generic competitors) is one example among many. The difference-in-differences method states that the policy of interest should not affect the control group. If the control group includes therapeutic competitors of products in the treatment group, the results are likely to be biased. One common practice is to calculate the robust standard errors clustered at the product or active ingredient level. One might argue that the prices are in fact clustered per therapeutic or chemical group. Chapters 4 and 5 take account of these challenges.

# 4 Data description

## 4.1 Data sources

My empirical analysis uses pharmaceutical pricing data received from the Association of Finnish Pharmacists (AoFP). The database from AoFP includes twice-a-month pricing data from all pharmaceuticals sold in Finnish pharmacies from April 2003 to May 2018.[19] I deflate the prices using the consumer price index provided by Statistics Finland, with the base level set to the year 2000. I also use data from Fimea and Hila to link the brand statuses and reference price groups to the pricing data. The data contain the prices at both the wholesale and retail levels. However, as retail prices are directly regulated by the government, I use the wholesale prices in my analysis and all later references to prices are in the wholesale level.

Each product is identified by its respective Nordic Article Number (VNR) and contains not just pricing information, but also various other product characteristics, such as reimbursement and prescription details. Each VNR code represents an individual package sold in pharmacies and has six distinct criteria: trade name, market authorisation holder, dosage form, strength, pack size, and type of package. A change in any of the criteria would require a new VNR code be issued.[20] Thus, any indirect price reactions, such as new pack sizes, are visible through new VNR entries in the data. However, my empirical strategy does not to follow these. I will discuss this briefly in Chapter 5.

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[19] Pharmaceutical pricing periods begin on the 1st and 15th day of each month.

[20] Pharmaceutical Information Centre, 2019.

I aggregate the data on monthly prices using the product characteristics from the first pricing period of each month. The aggregation is the average price within each month. I discharge all observations from OTC products and pharmaceuticals sold for animal use. As my empirical strategy is intended to analyse the possibility of the 'generic competition paradox' in relation to RP, the observations with missing brand statuses have been removed from the estimation. In addition, some products do not have information on their ATC classification. As discussed in Chapter 5, the standard errors are likely to be clustered within ATC4 groups, and therefore missing values cannot be accepted into the model. Thus, the observations with missing ATC statuses have been removed from the estimations.

Finally, I limit the data to the time period from the third quarter of 2006 to the end of 2012. This is due to the other reforms in the Finnish pharmaceutical market. As mentioned in Chapter 2, the Finnish government dictated mandatory wholesale price cuts at the start of 2006 and 2013. I isolated my data period by removing the periods before and after the aforementioned limits. I have chosen the third quarter in 2006 to ensure that no price adjustments are present in my data. As mentioned in Chapter 2, there were no changes in the reimbursement percentages during this period that could affect the price levels.

## 4.2 Defining control and treatment groups

The empirical analysis relies on the proper definitions of the treatment group and control group. In this chapter, I define the data sample used in my estimation. This is motivated by the time variant changes in the Finnish

legislation and the identifying assumptions of the empirical strategy discussed in Chapter 5.

The treatment group is coded to consist of all products assigned to an reference price group by Hila before 2017. The year threshold is due to a change in legislation that saw the Finnish Health Insurance Act allow the formation of an reference price group based on parallel imports and parallel-distributed products. During the period of 2009 to 2017, an reference price group could be formed only when there was direct generic competition. The control group consists of publicly reimbursed pharmaceuticals subject to generic competition that are not assigned to a reference price group. Thus, they are only subject to the normal reimbursement price cap (reasonable wholesale price) decided by Hila.

My criteria specify that all products must have been publicly reimbursed by the start of the second quarter of 2006. At the start of that year, the Finnish government forced a mandatory cut of 5% in prices for all publicly reimbursed products. Manufacturers were given a choice of either accepting the price cut or seeing the reimbursement withdrawn. My limitation ensures that the products were reimbursed and thus under the price cap regulation after the price cut. I also specify that products cannot have permanently exited the reimbursement system until after 2012.

Furthermore, I consider only those products that faced generic competition some years before the implementation of the RPS reform. This ensures that my estimations do not only capture the effect of generic competition or patent expiration. I calculate the number of generic competitors as that of different market authorisation holders within a substitution group during each time period. I consider generic competition to exist if more than one market

authorisation holder exists in the market. This broad definition also covers competition from parallel-imported products as generic competition. However, to allow possible market exits to remain in the data, I do not require the generic competition to be present in each period after the start. The limitation only requires that generic competition occurred at some point before the start of the second quarter of 2006, three years prior to the RPS reform. In the absence of reliable data on patent expiration, the requirement also ensures that all pharmaceuticals in the data sample are off-patent pharmaceuticals.

The products within the control group do not necessarily have generic competitors in every period, but they have certainly had them at some point. This is the only viable decision in light of the policy reform. As all products with at least one generic competitor after the policy change are assigned to the RPS, I cannot include a strict requirement for generic competition in all periods. The control group includes products that are (i) parallel imports, (ii) parallel-distributed products, or (iii) products with non-continuous generic competition. One can argue that this specification hinders comparability between the groups. I address these issues in the following chapter.

As explained in Chapter 5, a similarity in the composition of control and treatment groups is a preferred attribute to allow robust analysis of the estimates. At the same time, however, the two groups should not be so similar that the policy reform could also affect the control group. The problem arises from possible cross-price elasticities between products in the treatment and control groups, which could cause the control group to also react to the reform. Thus, competition between products in the control and treatment groups could create serious bias in my estimates. To counter this possibility, I have removed all ATC5 groups (same active ingredient) with observations in both the treat-

ment and control groups. As a final step, I have removed all ATC2 groups with products in only the treatment group or only the control group. The latter filter is applied so that the products in the control and treatment groups will not be too therapeutically different and thus differ greatly in their price trends.

As stated previously, the ATC5 level denotes a shared active ingredient. In the Finnish RPS, however, the substitution or reference price groups are not determined purely by a shared active ingredient, but also other characteristics such as pharmacological strength and pack size. The limitation at the ATC5 level thus means that the control group does not include different variations of an active ingredient otherwise included in the treatment group.

Filtering observations by ATC groups is a trade-off between the degree of therapeutic competition and common price trends. Brekke et al. (2009) used ATC2 classification to define therapeutic competition. This approach constitutes the strictest method of addressing the possible cross-price elasticities between the treatment and control groups. I have chosen to compare more therapeutically similar products and exclude competition between products with the same active ingredient. A more robust approach might use ATC4 groups instead. However, at this point, the limitations of my data are evident, as the control group would almost entirely vanish.

The final composition of the treatment and control groups is presented in Table 2. The prices in the control group are higher than those in the treatment group, which is explained by their different product compositions. The control group has a relatively small share of generic products, with only nine of the 75 being generics (excluding parallel imports). This is unsurprising, as almost all generics are assigned to the RPS. The small number of generics in the control

**Table 2:** Descriptive statistics

| | (1) Control group Mean/SD | (2) Treatment group Mean/SD |
|---|---|---|
| Pharmacy purchasing price | 36.03788 | 9.786098 |
| | 61.9919 | 17.97803 |
| Pharmacy retail price | 48.96428 | 14.47656 |
| | 76.8695 | 23.40587 |
| Products (vnr) | 75 | 649 |
| Generics | 26 | 457 |
| Parallel imports | 15 | 4 |
| ATC5 groups | 36 | 81 |
| Obs | 5824 | 52340 |

Descriptive statistics presented by treatment status. Prices deflated using the year 2000 as the base year.

group are likely to be those no longer considered substitutable by Fimea. However, there are 15 parallel-imported products in the control group. The remaining products in the control group are branded products no longer under patent protection. More than half of the products in the treatment group are generic. In addition, there are four parallel imports in the treatment group. They can be included into reference price groups but cannot constitute the foundation of a reference price group themselves.

# 5 The empirical strategy

## 5.1 Design and identifying assumptions

The empirical analysis of my thesis is intended to explain how the RPS reform affected pharmaceutical prices in Finland. The research makes use of the fact that not all publicly reimbursed products with substitutable competitors were assigned to the RPS at the start of the policy, thus creating a quasi-natural experiment. For instance, parallel-distributed products and parallel-imported products were partially excluded from the legislation when it was approved in late 2008.[21] Thus, some products remained within the previous price cap regulation and were not subject to the reference price regulation. Hypothetically, the reform provided an exogenous source of variation in pharmaceutical prices. Under the assumption that treatment assignment provided by the legislation was essentially random, I can estimate the causal effect of the reform using the difference-in-differences method. The principle of the method is simple: the control group provides a contrafactual on how the prices would have evolved in the treatment group, had the RPS reform not been implemented.

The main identifying assumption of the difference-in-differences method is the parallel trends assumption. More precisely, I assume that the treatment and control groups saw similar price trends during the pre-treatment period and, in the absence of treatment, they would have continued to evolve sim-

[21] As mentioned previously, parallel imports are the original products imported from other EU countries into Finland. Parallel-distributed products are parallel imports whose original product received its market authorisation through the centralised procedure.

ilarly in the post-treatment period. My second identifying assumption is the requirement that the treatment must not have affected the control group in the post-treatment period. Third, to estimate the effect of the reference price reform, there should not have been any other reforms that could have affected the control or treatment groups.

In the context of my thesis, it is thus required that the control and treatment group saw similar price trends before the implementation of the RPS. Figure A provides a visual interpretation of the price trends, supporting the first assumption. In the pre-treatment period, the two price paths are typically the same, while they differ more in the post-treatment period. The left-most red bar denotes September 2008, when the reference price reform reached the Finnish parliament; and the right-most bar represents April 2009, when the reference price policy took effect. Based on a visual interpretation, the use of the difference-in-difference method is suitable. I will test the assumption empirically and discuss its robustness in detail in Chapter 5.2.

The second identifying assumption is taken into account in the defining process of the data sample, as explained in Chapter 4.2. Limiting the data by excluding direct therapeutic competitors between the control and treatment groups should guarantee that there are no general equilibrium side-effects between the control and treatment groups. Thus, no cross-price elasticities should exist between the two groups.

The third assumption of other policy reforms is unfortunately not satisfied. However, this is not a severe violation. The issue arises from the reference price reform having included a stricter policy on generic substitution. As mentioned in Chapter 2, after the 2003 generic substitution reform, pharmacies were required to substitute pharmaceuticals for the cheapest substitutable product

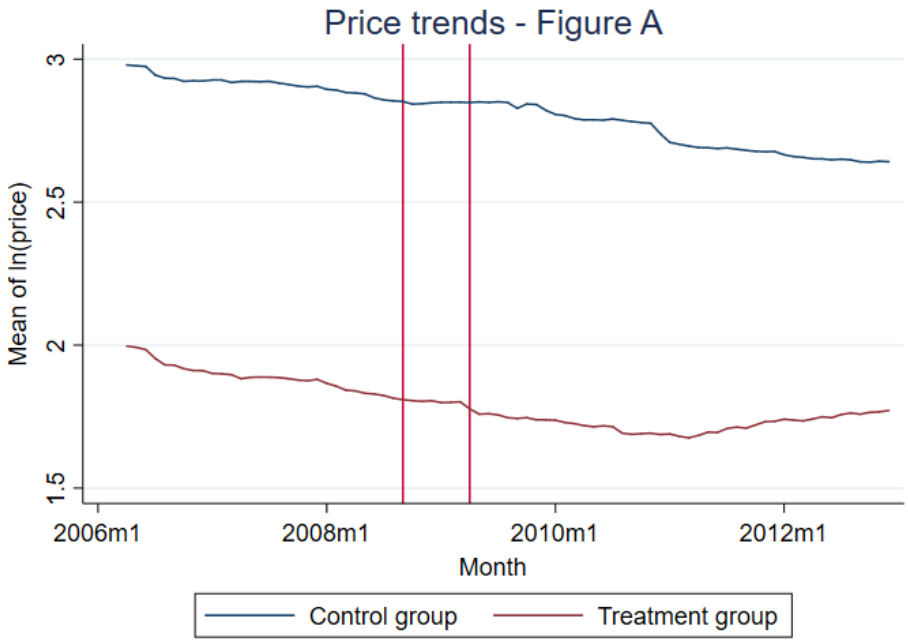


**Figure A:** Mean log prices by treatment status.

(or for one whose price differed only slightly from that of the cheapest product). Originally, the price corridor was limited to two euros if the total price were below 40 euros and to three euros for products above that limit. In the 2009 reform, the corridor was tightened to 1.50 euros and two euros, respectively. The implementation of the new price corridor began on 1 January 2009, in the quarter before the RPS reform. In theory, my empirical strategy will capture the effect of the change on the price corridor. This could affect both the control and treatment groups. However, I do not expect the problem to have major consequences for the results. This policy is tied to the Finnish regulatory environment and no previous literature exists on how the price corridor affects firms' pricing decisions. I assume this will be only a minor issue.

## 5.2 Estimation results

I replicate the study of Brekke et al. (2011). The similarities begin with the empirical strategy, policy reform, and the countries under study; but later, I make distinct departures from the existing work. Firstly, I use product-level data, rather than an aggregation at the ATC5 level. Secondly, Norwegian index pricing is applied to a smaller set of pharmaceuticals than in the Finnish RPS. Imposing some of the restrictions described in Chapter 4.2 would leave no control group. Thirdly, as discussed in Chapter 3.2, Brekke et al. (2011) include the number of generics and therapeutic competitors as control variables. However, these controls are likely to be endogenous because higher prices can be a signal of profitability in a market. Hence, I do not include them in any of my estimations.

The base model of my analysis is expressed in equation (1). I include product fixed effects to control for the unobserved time-invariant product characteristics that might affect the dependent variable. Secondly, I add time-fixed effects at the month level to control for common time variant effects on log prices. The third control variable is the wholesaler of the product, representing either Tamro or Oriola. The control variable for the wholesaler is justified since the wholesaler might be correlated with the time-variant product fixed effects. The coefficient $\beta_1$ in the first term captures the effect of the policy reform. The term $Treatment_i * Post_t$ takes the value 1 for the treatment group after September 2008, the month in which the legislation was introduced at the Finnish parliament. This definition accounts better for the possible anticipation effects, as the passing of the legislation was almost certain. (As mentioned in Chapter 2, the policy came into effect in the second quarter

of 2009.) Finally, the term $\epsilon_{it}$ denotes the time-variant unobserved product characteristics that affect the dependent variable.

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Post_t \\ + Post_t + Product_i + Month_t \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{1}$$

It is established in the economic literature that there exist heterogeneous consumer preferences between branded and generic pharmaceutical products (Pavcnik, 2002; Brekke et al., 2011; Kaiser et al., 2014). The latter argue that these preferences are time-invariant and thus captured by the product fixed effects. It can be argued that the price trends between branded and generic products are time-variant due to the different consumer demand they face, as discussed in Chapter 3. A full analysis would require the estimation of price elasticities of demand by time period and brand status, which is outside the scope of this paper.

Equation (1) is used to estimate the effect on all pharmaceuticals. However, in line with Brekke et al. (2011) and Kaiser et al. (2014), I add an interaction term between the differences-in-differences term and the product brand status to estimate whether the treatment effect differs for branded pharmaceuticals. With this minor modification, equation (1) becomes the following:

$$
\begin{aligned}
ln(Price)_{it} = \beta_1 * Treatment_i * Post_t \\
+ \beta_2 * Treatment_i * Post_t * Brand_i \\
+ Post_t * Brand_i \\
+ Product_i + Month_t \\
+ Wholesaler_{it} + \epsilon_{it}
\end{aligned} \tag{2}
$$

In both of my estimations, I account for auto-correlation between product prices and for correlation between a product and its generic and therapeutic competitors. In other words, I calculate the standard errors clustered within ATC4 groups.

The first results are shown in Table 3. Column (1) presents the standard difference-in-differences estimation without the brand interaction. The results show that prices fell by approximately 4.9% after the reference price policy was introduced in Finland. However, the estimate is not statistically significantly different from zero. Column (2) provides similar results when the effect is separated by brand status. I emphasise that the total effect on branded pharmaceuticals is the linear combination of the main effect and the brand interaction. However, this is not reported in the table. For branded pharmaceuticals, the effect of the policy change is a larger fall in prices, but the difference is small in magnitude and statistically significantly not different from zero. The estimate for the variable *Post* is statistically significant and approximately 20% in both estimations. This means that prices are, on average, 20% lower in the post-treatment period.

Comparing the regression estimates in Table 3 to the price trends in Figure A, it is clear that the treatment effect may differ between time periods. As

**Table 3:** Basic DID

| | (1) General | (2) By Brand Status |
|---|---|---|
| Treatment * Post | -0.0493 | -0.0225 |
| | (0.0395) | (0.0596) |
| Treatment * Post * Branded | | -0.0421 |
| | | (0.0558) |
| Post | -0.183*** | -0.208*** |
| | (0.0327) | (0.0461) |
| Wholesaler | 0.00472 | 0.00514 |
| | (0.0140) | (0.0142) |
| Product FE | Yes | Yes |
| Month FE | Yes | Yes |
| R2 | 0.134 | 0.134 |
| N | 58164 | 58164 |
| Clusters | 74 | 74 |

This table presents the results of the standard difference-in-differences regression. Column (1) presents the effect on all pharmaceuticals and column (2) indicates the effect separated by brand status. The estimation models are saturated. Robust standard errors, adjusted for clustering at ATC4 level, are presented in parentheses. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

shown in the Figure A, prices begin to climb upwards around 2011 in the treatment group. This allows me to hypothesise that the standard differences-in-differences model cannot capture the change in treatment effect over time.

I will now use a model that takes into account heterogeneous time period treatment effects. I use a yearly interaction with the treatment variable, setting the base year to 2008. This is a more aggregated version than a calculation of the treatment effects by quarter, which is the length of each reference price period. Due to the scope of my thesis, simpler regression tables are preferred, as the post-treatment period includes 16 quarters. As before, I will first estimate the overall effects and then the brand interaction. As before, the standard errors are adjusted for clusters in ATC4 groups. The two models can be written as follows:

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Year_{it} \\ + Product_i + Month_t \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{3}$$

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Year_t \\ + \beta_2 * Treatment_i * Year_i * Brand_i \\ + Year_i * Brand_i \\ + Product_i + Month_t \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{4}$$

The results for the yearly treatment effects are shown in Table 4. As expected, the results are more promising. Column (1) indicates that, compared to the control group, prices of pharmaceuticals in the treatment group fell by 5.9% in 2009 and 8.7% in 2010. The estimate for 2009 is statistically significant at the 1% level, and for 2010 at the 5% level. The magnitude and

**Table 4:** Yearly treatment effects

| | (1) | (2) |
|---|---|---|
| | General | By Brand Status |
| Treatment * 2009 | -0.0590** | -0.0472 |
| | (0.0182) | (0.0278) |
| Treatment * 2010 | -0.0869* | -0.0883 |
| | (0.0381) | (0.0538) |
| Treatment * 2011 | -0.0257 | -0.0126 |
| | (0.0487) | (0.0729) |
| Treatment * 2012 | 0.0752 | 0.123 |
| | (0.0444) | (0.0660) |
| Treatment * 2009 * Branded | | -0.0144 |
| | | (0.0324) |
| Treatment * 2010 * Branded | | 0.0286 |
| | | (0.0573) |
| Treatment * 2011 * Branded | | -0.00628 |
| | | (0.0663) |
| Treatment * 2012 * Branded | | -0.118* |
| | | (0.0560) |
| Wholesaler | 0.00894 | 0.00672 |
| | (0.0134) | (0.0144) |
| Product FE | Yes | Yes |
| Month FE | Yes | Yes |
| R2 | 0.138 | 0.144 |
| N | 58164 | 58164 |
| Clusters | 74 | 74 |

This table presents the yearly treatment effects on log prices. Column (1) presents the effect on all pharmaceuticals and column (2) gives the effect by brand status. The estimation models are saturated. Robust standard errors, adjusted for clustering at ATC4 level, are presented in parentheses. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

the sign of the results is in line with the findings in the previous economic literature. The results indicate that the treatment effect decreases for 2011 and becomes a positive estimate for 2012. However, neither estimate for 2011 or 2012 is statistically significantly different from zero. In conclusion, the implementation of the reference price reform lowered prices in 2009 and 2010, but had no statistically significant effect in 2011 or 2012.

Column (2) presents that the yearly treatment effects for generics and branded pharmaceuticals. As before, the total effect on branded pharmaceuticals is the linear combination of the main effect and the brand interaction. The first observation is that, in 2009, 2011, and 2012, the interaction term is negative. Most notably, the effect is -1.4 percentage points in 2009 and -11.8 percentage points in 2012. Thus, the price effects seem to be more driven by branded pharmaceuticals than generics. Taken at face value, the results provide counter-evidence of the generic competition paradox. However, only the interaction term in 2012 is statistically significantly different from zero at the 5% level; thus, we cannot reject the null hypothesis that the effect of reference price is the same for both branded and generic products for the rest of the years. However, the price increases in 2012 seem to be driven by generic products.

The results in column (2) do not directly imply that the treatment effect would be different for the two product groups. While this could be the case, my empirical strategy does not allow us statistically to conclude this. It is possible that a larger sample would allow more precise estimations to test whether the effect is different between generics and branded products.

## 5.3 Robustness checks

To empirically test the parallel trends assumption, I regress the log prices on the month*treatment interaction and month-specific dummy indicators. The model and the monthly treatment effects are given in the Appendix. Figure B illustrates the monthly marginal effects between the treatment and control group. The graph shows that, in the pre-treatment period, each individual month interaction with the treatment variable is statistically significantly not different from zero. The two red bars in Figure B denote the months when the reform was introduced in the Finnish parliament and came into force. A clear anticipation effect is seen after September 2008, with prices beginning to decline before the implementation of the policy.

Unfortunately, the interactions in the pre-treatment period do not satisfy the F-test for joint significance. The F-statistic has a value of 7.00, with 29 restrictions and 73 degrees of freedom. This corresponds to an almost zero p-value. Thus, the null hypothesis that all treatment–month interactions in the pre-treatment period would be equal to zero is rejected. This result directly contradicts the parallel trends assumption. Assessed conservatively, I cannot reject the possibility that the price trends in the control and treatment groups would significantly differ in the pre-treatment period. Thus, the control group does not provide a contrafactual that would allow causal interpretation of the results.

Nevertheless, the use of the F-test for joint significance in this thesis stands out from the existing empirical literature. For example, Herr and Suppliet (2017), Brekke et al. (2011) and Pavcnik (2002) test empirically for joint significance, but their F-tests were based solely on a regression of the pre-treatment

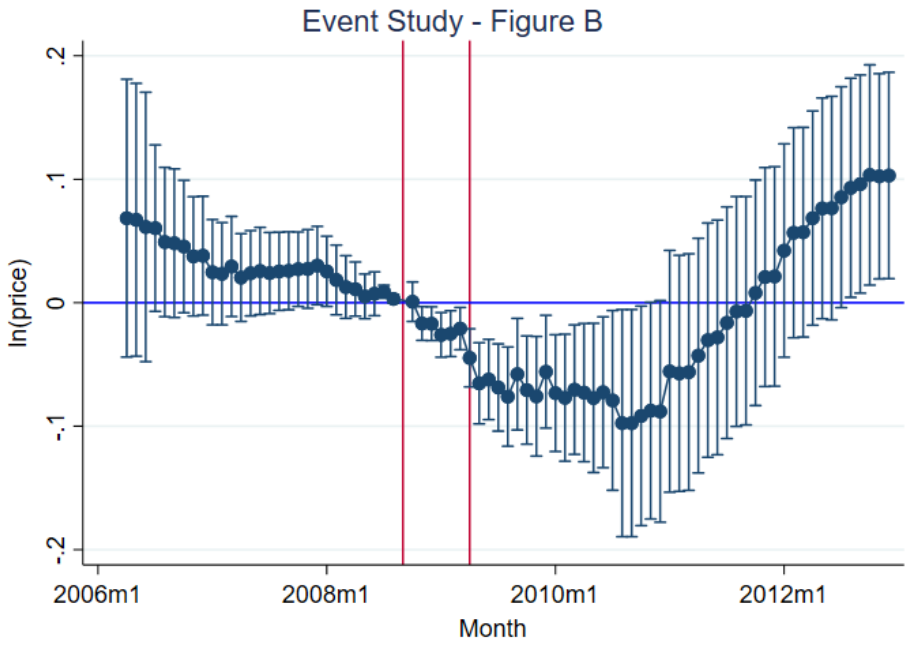


**Figure B:** Monthly treatment effect on log prices. Confidence interval at 95% level. Standard month fixed effects.

period. Limiting the data to fewer observations intuitively increases the standard errors of the estimates. Conducting the test for joint significance this way provides an F-statistic with a value of 7.73 and a zero p-value. Despite the intuition, the resulting F-statistic is larger and worse for the main identifying assumption.

Another explanation could lie in the clustering of standard errors. I have chosen to apply clustering within ATC4 groups, which accounts for the correlation between similar products, in contrast to robust standard errors at either package or ATC5 level. Secondly, the composition of data could also affect the results. Unlike Brekke et al. (2011), I do not aggregate my data within ATC5 active ingredients and brand statuses, but rather use the package-level

data. The aggregation destroys much of the variation within the data. This can be seen in the mean prices calculated by Brekke et al. (2011) for the ATC5 groups: they have standard errors of different magnitudes. I argue that Brekke et al. (2011) should have included a robustness check of whether the results would be changed by package-level data.

However, the results of the F-test are unsurprising, given the different compositions of the control and treatment groups. The control group is largely composed of branded pharmaceuticals, in contrast to the treatment group, and pricing trends between original and generic products are expected to be inherently different. A possible change to the specifications would be to use more flexible time-fixed effects. To test this, I regress the log prices on the month*treatment interaction and month*brand*ATC2 interaction dummies. Again, the specific model and regression results are presented in the Appendix. The results are shown visually in Figure C. In comparison to Figure B, the estimates of the marginal treatment effects in the pre-treatment period are closer to zero. As before, each individual month in the pre-treatment period is not statistically significantly different from zero. However, the joint significance remains, as denoted by the value F-statistics (5.60) and p-value at zero. I do not regress the models from equations (1)–(4) with the new month–fixed effect specification because, even with the more flexible model, the estimations are not sufficiently robust for causal interpretation.

I previously hypothesised that brand preferences and demand compositions of branded and generic pharmaceuticals could in fact be time-variant. I also addressed the issue regarding the filtering of therapeutic competitors at the ATC5 level. Although the regression shown in Figure C does not save the identifying assumption of my empirical strategy, it does verify the existence

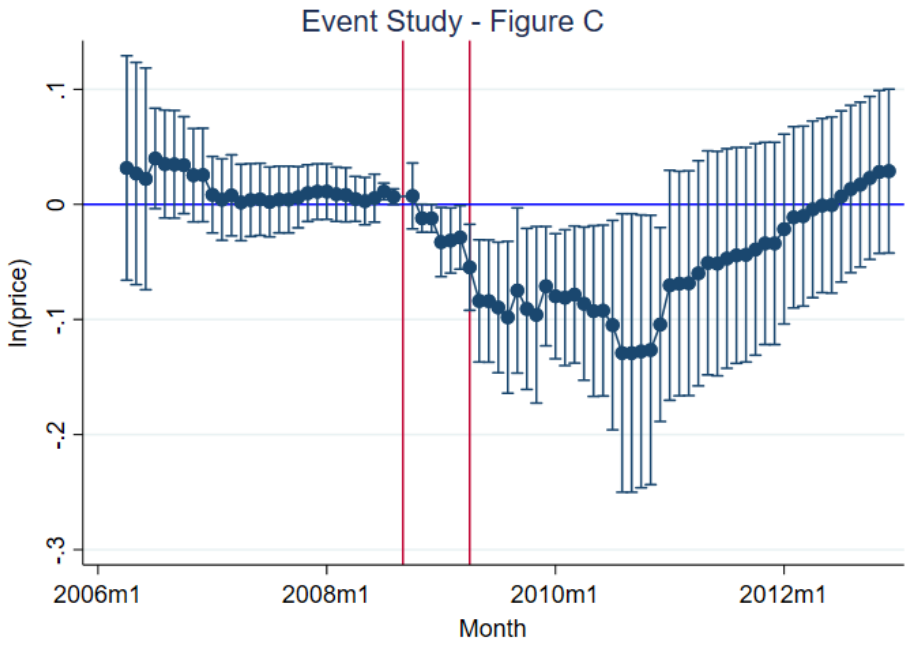


**Figure C:** Monthly treatment effect on log prices. Confidence interval at 95% level. Flexible month fixed effects.

of heterogeneous time trends in terms of brand statuses and therapeutic subgroups. However, the addition of several dummy variables per brand status and ATC2 group for each month is not a preferred estimation strategy. Time-fixed effects that are too flexible take in more variation; and if not properly justified, this could lead to biased estimates.

As a final robustness check, I aggregate the data to the quarterly level, and run the same two robustness checks mentioned above. The prices are calculated as the average within the quarter and the product characteristics are taken from the first pricing period of each quarter. The models, regression tables and graphs are provided in the Appendix. This time the test on joint significance passes: the F-statistics get the values 1.02 and 0.65 with

the corresponding p-values of 0.43 and 0.73. Thus, a more aggregated model can provide results that allow causal interpretation. It is important to notice that both Pavcnik (2002) and Brekke et al. (2011) use quarterly aggregation and get similar scores for their F-statistics. Again, the quarterly aggregation destroys some of the variation within the data. At the same time, the F-test on monthly estimates carries three times more linear restrictions than in the quarterly aggregation. It is possible that the test for joint significance is too strict for the monthly data just because it has more data points for the same time frame.

It is difficult to make any robust conclusions from the quarterly regressions. The results are in line with the previous empirical literature in terms of magnitude and the rejection of joint significance in the pre-treatment period. However, they also contradict the results of the monthly estimations pulled from the same data sample. I take the conservative approach and conclude that the monthly aggregation provides a more robust approach than the quarterly data. The quarterly aggregations suggest that some of the results from previous empirical literature should perhaps be taken with a grain of salt.

# 6 Discussion

The results of my empirical analysis are in line with both my theoretical predictions and the results of past empirical research. Initially, the Finnish reference price reform lowered pharmaceutical prices. My results do not verify the existence of the generic competition paradox, but neither does they provide evidence against it. However, this is unsurprising in light of the contradicting results in the previous empirical literature. My results suggest that the Finnish reference price reform induced price decreases in 2009 and 2010, with the effect gradually replaced by price increases. A possible explanation for this is that RP eventually leads to increases in market exits and reduction in competition. This should be reflected in the data as a decrease in the average size of the substitution groups over time. A testing of this hypothesis, however, is out of the scope of this thesis.

Unfortunately, the crucial identifying assumption of parallel price trends is not satisfied; and as a result, a causal interpretation of the price decreases and the RPS reform is not possible. It is important to note that the problem is not necessarily due to the model, but rather the context of the Finnish reform. Unlike in the case of the Norwegian 2003–2005 index pricing, the Finnish regulation left no proper control group in the market. My empirical strategy attempts to balance between this limitation and the identifying assumptions of the difference-in-differences strategy. My empirical strategy provides a robust estimation of the Finnish reference price reform. This is achieved by using rich, product-level panel data without unnecessary aggregation, proper clustering of standard errors, and tests for the identifying assumptions. The takeaway of this thesis does not lie in the estimates. Rather, its main contribution is

its analysis of how the effects of a policy experiment such as the Finnish RPS should be evaluated.

As previously discussed, defining an appropriate control group is a difficult task when using Finnish data. The straightforward recommendation would be to use cross-country data. This could be achieved by comparing the Finnish products subject to reference price with the same products (at the package level) in another country. Since Finland adopted RP some years after its Nordic peers in Denmark and Norway, comparing Finnish pharmaceutical markets to their counterparts in either of these countries would be a viable solution. However, I leave this for future research.

The data sample of my thesis is defined at the individual package level, as discussed in Chapter 4. This specification restricts the potential to study indirect price reactions through changes in pack sizes and types. These reactions should be visible in the data in the form of new VNR codes and reference price groups. However, the product-level requirements for generic substitution and public reimbursement do not allow to follow these changes in my empirical strategy. A more aggregated definition of a pharmaceutical product could capture more of the effects of the RPS. However, changes in pack size face greater inertia on the regulator's side, since public reimbursement is defined at the VNR level. As discussed in Chapter 2, a new reimbursement decision from the Pharmaceutical Pricing Board for new products could require up to 180 days. New pack sizes could also require changes in market authorisation for the products. Thus, it is safe to assume that the transaction costs are lower for direct price reactions than for changes in product characteristics.

RP is an indirect policy tool for controlling pharmaceutical prices. It affects the competitive environment by changing the elasticity of demand above the

reference price. If my empirical results are taken at face value, they indicate that the RPS policy induced price decreases in its first two years. However, Finland is a small country with a small pharmaceutical market. Decreasing the profitability of the Finnish pharmaceutical market could decrease competition, by both increasing exits and discouraging entries. The latter could explain the change in the treatment effect after 2010.

The design of the reference price policy should also be addressed. The Finnish system differs from that of its Nordic peers in Denmark and Sweden, with its quarter-long reference price period and use of a price corridor. My thesis is not designed to consider the effects of the latter two, but it can hypothesise that these structures decrease competition both within the reference price period and the price corridor.

# 7 Conclusions

IRP is the most efficient form of RP. In comparison to ERP, the IPR system avoids clustering of prices around the reference price by making pricing decisions of firms endogenous in nature. However, even for internal RP, there are differences in the regulatory approaches adopted by different countries. The Finnish RPS utilises internal RP, but it also includes some unique characteristics based in its institutional environment.

As a result of pharmaceutical RP, prices in Finland decreased by 5.9% and 8.7% during 2009 and 2010. This effect disappeared in 2011, and price increases were seen in 2012. I find no strict evidence that the price effects would differ for branded and generic pharmaceuticals. However, the Finnish RPS reform constitutes a weak quasi-experiment, as almost all products facing generic competition entered the RPS. The main identifying assumption of parallel price trends for products in the treatment and control groups is not satisfied, which means the results cannot be interpreted causally.

Based on the results seen here, the Finnish RPS provides evidence that, after initial price decreases, RP leads to price increases. It can be hypothesised that this is the result of market exits and decreases in competition. If so, policy-makers should further evaluate whether pharmaceutical RP has the disadvantage of deterring new entries of products and firms into the market. A country such as Finland constitutes only a small market for large international manufacturers. This lesson has real relevance for policy-makers, as the entry of new products into existing pharmaceutical markets, as well as stable supply and competition, are crucial for efficient patient health care. Regulators should

address these indirect effects when designing a regulatory environment.

A more robust empirical strategy for analysing the effects of different reference price reforms is a cross-country difference-in-differences method. The products in the control group would be the counterparts of those in the domestic market in another country. In the case of the Finnish reference price reform, a possible baseline could be acquired by linking the Finnish products subject to RP to the same products sold in Denmark, for instance. This could increase the internal validity of the estimations. Ideally, the data would also include sold volumes, thus allowing proper welfare analysis to be reached.

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# Glossary

**Anatomical Therapeutic Chemical classification system**

A system that categorises pharmaceutical products into five levels based on their therapeutic, pharmacological and chemical properties.

**branded product**

A product that is manufactured by the original patent or market authorisation holder.

**external price referencing**

See external reference pricing.

**external reference pricing**

A reimbursement policy in which the reference price or maximum reimbursement is calculated as a benchmark from prices in non-domestic markets.

**generic product**

A chemically and threrapeutically equivalent copy of the original pharmaceutical product. Manufactured by a firm other than the original market authorisation holder.

**generic substitution**

Substitution between interchangeable products at the pharmacy, most often between branded and generic products.

**internal price referencing**

See internal reference pricing.

**internal reference pricing**

A reimbursement policy in which the reference price or maximum reimbursement is calculated from prices in the domestic market.

**parallel distributed product**

A parallel import of an original product that received its market authorisation through the centralised procedure.

**parallel import**

An original product that is exported by a firm other than the original market authorisation holder from a country to another in order to exploit an existing price arbitrage.

**price corridor**

determines the price difference of the cheapest substitutable product and a slightly more expensive alternative.

**reference pricing system**

A reimbursement policy in which the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine.

**therapeutic competition**

Competition between pharmaceutical products that have different active ingredients but are used for the treatment of a same disease.

# Acronyms

**AoFP**

Association of Finnish Pharmacists.

**ATC**

Anatomical Therapeutic Chemical classification system.

**CAD**

coronary artery disease.

**EMA**

European Medicines Agency.

**EPR**

external price referencing.

**EPR**

internal price referencing.

**ERP**

external reference pricing.

**EU**

European Union.

**Fimea**

Finnish Medicines Agency.

**Hila**

Finnish Pharmaceuticals Pricing Board.

**IRP**

internal reference pricing.

**Kela**

Finnish Social Insurance Institution.

**OTC**

over-the-counter pharmaceuticals.

**RP**

reference pricing.

**RPS**

reference pricing system.

**VAT**

value added tax.

**VNR**

Nordic Article Number.

**WHO**

World Health Organization.

# A Appendix

## A.1 Flexible difference-in-differences estimations

The following tables provide both the monthly and quarterly treatment effects on log prices both in the pre-treatment and post-treatment periods to test the parallel trends assumption discussed in Chapter 5. The regression equations are shown before the tables. The graphs for the quarterly regressions can be found after the tables.

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Month_t \\ + Product_i + Month_t \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{5}$$

**Table 5:** Flexible DID - Normal month fixed effects

| | (1) | |
|---|---|---|
| | ln(Price) | |
| Treatment * 2006m4 | 0.0685 | (0.0574) |
| Treatment * 2006m5 | 0.0672 | (0.0564) |
| Treatment * 2006m6 | 0.0614 | (0.0556) |
| Treatment * 2006m7 | 0.0604 | (0.0344) |
| Treatment * 2006m8 | 0.0492 | (0.0309) |
| Treatment * 2006m9 | 0.0482 | (0.0307) |
| Treatment * 2006m10 | 0.0455 | (0.0274) |
| Treatment * 2006m11 | 0.0376 | (0.0246) |

| | | |
|---|---|---|
| Treatment * 2006m12 | 0.0381 | (0.0245) |
| Treatment * 2007m1 | 0.0247 | (0.0218) |
| Treatment * 2007m2 | 0.0234 | (0.0211) |
| Treatment * 2007m3 | 0.0294 | (0.0207) |
| Treatment * 2007m4 | 0.0204 | (0.0181) |
| Treatment * 2007m5 | 0.0239 | (0.0176) |
| Treatment * 2007m6 | 0.0257 | (0.0180) |
| Treatment * 2007m7 | 0.0240 | (0.0168) |
| Treatment * 2007m8 | 0.0254 | (0.0162) |
| Treatment * 2007m9 | 0.0259 | (0.0161) |
| Treatment * 2007m10 | 0.0272 | (0.0154) |
| Treatment * 2007m11 | 0.0274 | (0.0162) |
| Treatment * 2007m12 | 0.0301 | (0.0162) |
| Treatment * 2008m1 | 0.0254 | (0.0145) |
| Treatment * 2008m2 | 0.0185 | (0.0144) |
| Treatment * 2008m3 | 0.0127 | (0.0130) |
| Treatment * 2008m4 | 0.0110 | (0.0112) |
| Treatment * 2008m5 | 0.00513 | (0.00922) |
| Treatment * 2008m6 | 0.00728 | (0.00906) |
| Treatment * 2008m7 | 0.00893** | (0.00268) |
| Treatment * 2008m8 | 0.00310 | (0.00181) |
| Treatment * 2008m9 | 0 | (.) |
| Treatment * 2008m10 | 0.000809 | (0.00816) |
| Treatment * 2008m11 | -0.0168* | (0.00699) |
| Treatment * 2008m12 | -0.0170* | (0.00697) |
| Treatment * 2009m1 | -0.0260** | (0.00922) |

| | | |
|---|---|---|
| Treatment * 2009m2 | -0.0250** | (0.00946) |
| Treatment * 2009m3 | -0.0209* | (0.00874) |
| Treatment * 2009m4 | -0.0446*** | (0.0120) |
| Treatment * 2009m5 | -0.0653*** | (0.0168) |
| Treatment * 2009m6 | -0.0622*** | (0.0166) |
| Treatment * 2009m7 | -0.0687*** | (0.0180) |
| Treatment * 2009m8 | -0.0760*** | (0.0205) |
| Treatment * 2009m9 | -0.0579* | (0.0231) |
| Treatment * 2009m10 | -0.0707** | (0.0224) |
| Treatment * 2009m11 | -0.0758** | (0.0247) |
| Treatment * 2009m12 | -0.0559* | (0.0233) |
| Treatment * 2010m1 | -0.0732** | (0.0241) |
| Treatment * 2010m2 | -0.0770** | (0.0262) |
| Treatment * 2010m3 | -0.0704* | (0.0268) |
| Treatment * 2010m4 | -0.0728* | (0.0286) |
| Treatment * 2010m5 | -0.0771* | (0.0308) |
| Treatment * 2010m6 | -0.0725* | (0.0312) |
| Treatment * 2010m7 | -0.0791* | (0.0371) |
| Treatment * 2010m8 | -0.0975* | (0.0469) |
| Treatment * 2010m9 | -0.0975* | (0.0469) |
| Treatment * 2010m10 | -0.0916* | (0.0453) |
| Treatment * 2010m11 | -0.0874 | (0.0448) |
| Treatment * 2010m12 | -0.0880 | (0.0458) |
| Treatment * 2011m1 | -0.0556 | (0.0500) |
| Treatment * 2011m2 | -0.0572 | (0.0488) |
| Treatment * 2011m3 | -0.0561 | (0.0489) |

| | | |
|---|---|---|
| Treatment * 2011m4 | -0.0428 | (0.0485) |
| Treatment * 2011m5 | -0.0303 | (0.0484) |
| Treatment * 2011m6 | -0.0281 | (0.0485) |
| Treatment * 2011m7 | -0.0162 | (0.0479) |
| Treatment * 2011m8 | -0.00711 | (0.0475) |
| Treatment * 2011m9 | -0.00652 | (0.0472) |
| Treatment * 2011m10 | 0.00802 | (0.0466) |
| Treatment * 2011m11 | 0.0208 | (0.0452) |
| Treatment * 2011m12 | 0.0213 | (0.0454) |
| Treatment * 2012m1 | 0.0422 | (0.0441) |
| Treatment * 2012m2 | 0.0566 | (0.0434) |
| Treatment * 2012m3 | 0.0571 | (0.0433) |
| Treatment * 2012m4 | 0.0685 | (0.0443) |
| Treatment * 2012m5 | 0.0764 | (0.0456) |
| Treatment * 2012m6 | 0.0766 | (0.0462) |
| Treatment * 2012m7 | 0.0854 | (0.0457) |
| Treatment * 2012m8 | 0.0931* | (0.0453) |
| Treatment * 2012m9 | 0.0961* | (0.0451) |
| Treatment * 2012m10 | 0.103* | (0.0455) |
| Treatment * 2012m11 | 0.102* | (0.0424) |
| Treatment * 2012m12 | 0.103* | (0.0426) |
| Product FE | Yes | |
| Month FE | Yes | |
| R2 | 0.139 | |
| N | 58164 | |

| | |
|---|---|
| Clusters | 74 |
| F-statistic | 7.002 |

This table presents the results from a flexible difference-in-differences regression. The F-test for joint significance is calculated for the pre-treatment period. Robust standard errors, adjusted for clustering at ATC4 level, are presented in parentheses. $^{*}$ $p < 0.05$, $^{**}$ $p < 0.01$, $^{***}$ $p < 0.001$

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Month_t \\ + Product_i \\ + Month_t * ATC2_i \\ + Month_t * Brand_i \\ + Month_t * Brand_i * ATC2_i \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{6}$$

**Table 6:** Flexible DID - Flexible month fixed effects

| | (1) | |
|---|---|---|
| | ln(Price) | |
| Treatment * 2006m4 | 0.0316 | (0.0498) |
| Treatment * 2006m5 | 0.0268 | (0.0493) |
| Treatment * 2006m6 | 0.0222 | (0.0491) |
| Treatment * 2006m7 | 0.0399 | (0.0223) |

| | | |
|---|---|---|
| Treatment * 2006m8 | 0.0350 | (0.0239) |
| Treatment * 2006m9 | 0.0348 | (0.0239) |
| Treatment * 2006m10 | 0.0341 | (0.0215) |
| Treatment * 2006m11 | 0.0253 | (0.0207) |
| Treatment * 2006m12 | 0.0256 | (0.0207) |
| Treatment * 2007m1 | 0.00837 | (0.0170) |
| Treatment * 2007m2 | 0.00413 | (0.0180) |
| Treatment * 2007m3 | 0.00782 | (0.0180) |
| Treatment * 2007m4 | 0.00165 | (0.0170) |
| Treatment * 2007m5 | 0.00377 | (0.0161) |
| Treatment * 2007m6 | 0.00438 | (0.0160) |
| Treatment * 2007m7 | 0.00210 | (0.0155) |
| Treatment * 2007m8 | 0.00418 | (0.0148) |
| Treatment * 2007m9 | 0.00418 | (0.0148) |
| Treatment * 2007m10 | 0.00624 | (0.0136) |
| Treatment * 2007m11 | 0.00977 | (0.0126) |
| Treatment * 2007m12 | 0.0111 | (0.0124) |
| Treatment * 2008m1 | 0.0111 | (0.0123) |
| Treatment * 2008m2 | 0.00881 | (0.0120) |
| Treatment * 2008m3 | 0.00834 | (0.0120) |
| Treatment * 2008m4 | 0.00477 | (0.00997) |
| Treatment * 2008m5 | 0.00283 | (0.0105) |
| Treatment * 2008m6 | 0.00538 | (0.0106) |
| Treatment * 2008m7 | 0.0113** | (0.00369) |
| Treatment * 2008m8 | 0.00665 | (0.00346) |
| Treatment * 2008m9 | 0 | (.) |

| | | |
|---|---|---|
| Treatment * 2008m10 | 0.00732 | (0.0146) |
| Treatment * 2008m11 | -0.0120 | (0.00621) |
| Treatment * 2008m12 | -0.0122 | (0.00619) |
| Treatment * 2009m1 | -0.0328* | (0.0153) |
| Treatment * 2009m2 | -0.0314* | (0.0144) |
| Treatment * 2009m3 | -0.0287* | (0.0141) |
| Treatment * 2009m4 | -0.0546** | (0.0191) |
| Treatment * 2009m5 | -0.0839** | (0.0271) |
| Treatment * 2009m6 | -0.0840** | (0.0271) |
| Treatment * 2009m7 | -0.0896** | (0.0290) |
| Treatment * 2009m8 | -0.0981** | (0.0337) |
| Treatment * 2009m9 | -0.0748* | (0.0366) |
| Treatment * 2009m10 | -0.0908* | (0.0357) |
| Treatment * 2009m11 | -0.0959* | (0.0391) |
| Treatment * 2009m12 | -0.0711** | (0.0265) |
| Treatment * 2010m1 | -0.0798** | (0.0277) |
| Treatment * 2010m2 | -0.0811** | (0.0301) |
| Treatment * 2010m3 | -0.0784* | (0.0304) |
| Treatment * 2010m4 | -0.0863* | (0.0339) |
| Treatment * 2010m5 | -0.0927* | (0.0378) |
| Treatment * 2010m6 | -0.0923* | (0.0379) |
| Treatment * 2010m7 | -0.105* | (0.0464) |
| Treatment * 2010m8 | -0.129* | (0.0617) |
| Treatment * 2010m9 | -0.129* | (0.0617) |
| Treatment * 2010m10 | -0.128* | (0.0605) |
| Treatment * 2010m11 | -0.126* | (0.0597) |

| | | |
|---|---|---|
| Treatment * 2010m12 | -0.104* | (0.0430) |
| Treatment * 2011m1 | -0.0703 | (0.0510) |
| Treatment * 2011m2 | -0.0688 | (0.0498) |
| Treatment * 2011m3 | -0.0685 | (0.0498) |
| Treatment * 2011m4 | -0.0599 | (0.0499) |
| Treatment * 2011m5 | -0.0508 | (0.0496) |
| Treatment * 2011m6 | -0.0514 | (0.0498) |
| Treatment * 2011m7 | -0.0470 | (0.0487) |
| Treatment * 2011m8 | -0.0443 | (0.0479) |
| Treatment * 2011m9 | -0.0437 | (0.0476) |
| Treatment * 2011m10 | -0.0391 | (0.0469) |
| Treatment * 2011m11 | -0.0339 | (0.0448) |
| Treatment * 2011m12 | -0.0339 | (0.0448) |
| Treatment * 2012m1 | -0.0215 | (0.0421) |
| Treatment * 2012m2 | -0.0113 | (0.0402) |
| Treatment * 2012m3 | -0.0102 | (0.0399) |
| Treatment * 2012m4 | -0.00431 | (0.0392) |
| Treatment * 2012m5 | -0.000972 | (0.0386) |
| Treatment * 2012m6 | -0.000582 | (0.0391) |
| Treatment * 2012m7 | 0.00688 | (0.0379) |
| Treatment * 2012m8 | 0.0134 | (0.0371) |
| Treatment * 2012m9 | 0.0172 | (0.0365) |
| Treatment * 2012m10 | 0.0229 | (0.0361) |
| Treatment * 2012m11 | 0.0282 | (0.0361) |
| Treatment * 2012m12 | 0.0289 | (0.0363) |

| | |
|---|---|
| Product FE | Yes |
| Month FE | Yes |
| R2 | 0.356 |
| N | 58164 |
| Clusters | 74 |
| F-statistic | 5.602 |

This table presents the results from a flexible difference-in-differences regression. The model includes flexible month fixed effects with interactions per ATC2 groups and brand status. The F-test for joint significance is calculated for the pre-treatment period. Robust standard errors, adjusted for clustering at ATC4 level, are presented in parentheses. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Quarter_t \\ + Product_i + Quarter_t \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{7}$$

**Table 7:** Flexible DID - Normal quarter fixed effects

| | (1) | |
|---|---|---|
| | ln(Price) | |
| Treatment * 2006q3 | 0.0496 | (0.0318) |
| Treatment * 2006q4 | 0.0365 | (0.0250) |

| | | |
|---|---|---|
| Treatment * 2007q1 | 0.0219 | (0.0209) |
| Treatment * 2007q2 | 0.0196 | (0.0178) |
| Treatment * 2007q3 | 0.0266 | (0.0171) |
| Treatment * 2007q4 | 0.0255 | (0.0157) |
| Treatment * 2008q1 | 0.0159 | (0.0136) |
| Treatment * 2008q2 | 0.00426 | (0.00902) |
| Treatment * 2008q3 | 0 | (.) |
| Treatment * 2008q4 | -0.00809 | (0.00675) |
| Treatment * 2009q1 | -0.0256** | (0.00784) |
| Treatment * 2009q2 | -0.0594*** | (0.0144) |
| Treatment * 2009q3 | -0.0710*** | (0.0192) |
| Treatment * 2009q4 | -0.0716** | (0.0216) |
| Treatment * 2010q1 | -0.0759** | (0.0250) |
| Treatment * 2010q2 | -0.0760* | (0.0296) |
| Treatment * 2010q3 | -0.0925* | (0.0426) |
| Treatment * 2010q4 | -0.0847* | (0.0396) |
| Treatment * 2011q1 | -0.0582 | (0.0485) |
| Treatment * 2011q2 | -0.0356 | (0.0478) |
| Treatment * 2011q3 | -0.0119 | (0.0470) |
| Treatment * 2011q4 | 0.0151 | (0.0451) |
| Treatment * 2012q1 | 0.0499 | (0.0431) |
| Treatment * 2012q2 | 0.0735 | (0.0449) |
| Treatment * 2012q3 | 0.0906* | (0.0452) |
| Treatment * 2012q4 | 0.104* | (0.0441) |
| Product FE | Yes | |

| | |
|---|---|
| Quarter FE | Yes |
| R2 | 0.127 |
| N | 18681 |
| Clusters | 74 |
| F-statistic | 1.020 |

This table presents the results from a flexible difference-in-differences regression. The F-test for joint significance is calculated for the pre-treatment period. Robust standard errors, adjusted for clustering at ATC4 level, are presented in parentheses. $^{*}$ $p < 0.05$, $^{**}$ $p < 0.01$, $^{***}$ $p < 0.001$

$$\begin{aligned} ln(Price)_{it} = \beta_1 * Treatment_i * Quarter_t \\ + Product_i \\ + Quarter_t * ATC2_i \\ + Quarter_t * Brand_i \\ + Quarter_t * Brand_i * ATC2_i \\ + Wholesaler_{it} + \epsilon_{it} \end{aligned} \tag{8}$$

**Table 8:** Flexible DID - Flexible quarter fixed effects

| | (1) | |
|---|---|---|
| | ln(Price) | |
| Treatment * 2006q3 | 0.0304 | (0.0234) |

| | | |
|---|---|---|
| Treatment * 2006q4 | 0.0218 | (0.0208) |
| Treatment * 2007q1 | 0.000161 | (0.0173) |
| Treatment * 2007q2 | -0.00306 | (0.0160) |
| Treatment * 2007q3 | 0.00453 | (0.0156) |
| Treatment * 2007q4 | 0.00376 | (0.0124) |
| Treatment * 2008q1 | 0.00384 | (0.0118) |
| Treatment * 2008q2 | -0.00426 | (0.00895) |
| Treatment * 2008q3 | 0 | (.) |
| Treatment * 2008q4 | -0.00353 | (0.0145) |
| Treatment * 2009q1 | -0.0339* | (0.0133) |
| Treatment * 2009q2 | -0.0774** | (0.0235) |
| Treatment * 2009q3 | -0.0930** | (0.0320) |
| Treatment * 2009q4 | -0.0923** | (0.0330) |
| Treatment * 2010q1 | -0.0848** | (0.0295) |
| Treatment * 2010q2 | -0.0952* | (0.0367) |
| Treatment * 2010q3 | -0.125* | (0.0559) |
| Treatment * 2010q4 | -0.123* | (0.0526) |
| Treatment * 2011q1 | -0.0747 | (0.0503) |
| Treatment * 2011q2 | -0.0592 | (0.0497) |
| Treatment * 2011q3 | -0.0505 | (0.0480) |
| Treatment * 2011q4 | -0.0408 | (0.0453) |
| Treatment * 2012q1 | -0.0213 | (0.0406) |
| Treatment * 2012q2 | -0.00637 | (0.0387) |
| Treatment * 2012q3 | 0.00754 | (0.0370) |
| Treatment * 2012q4 | 0.0218 | (0.0361) |

| | |
|---|---|
| Product FE | Yes |
| Quarter FE | Yes |
| R2 | 0.343 |
| N | 18681 |
| Clusters | 74 |
| F-statistic | 0.649 |

This table presents the results from a flexible difference-in-differences regression. The model includes flexible quarter fixed effects with interactions per ATC2 groups and brand status. The F-test for joint significance is calculated for the pre-treatment period. Robust standard errors, adjusted for clustering at ATC4 level, are presented in parentheses. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

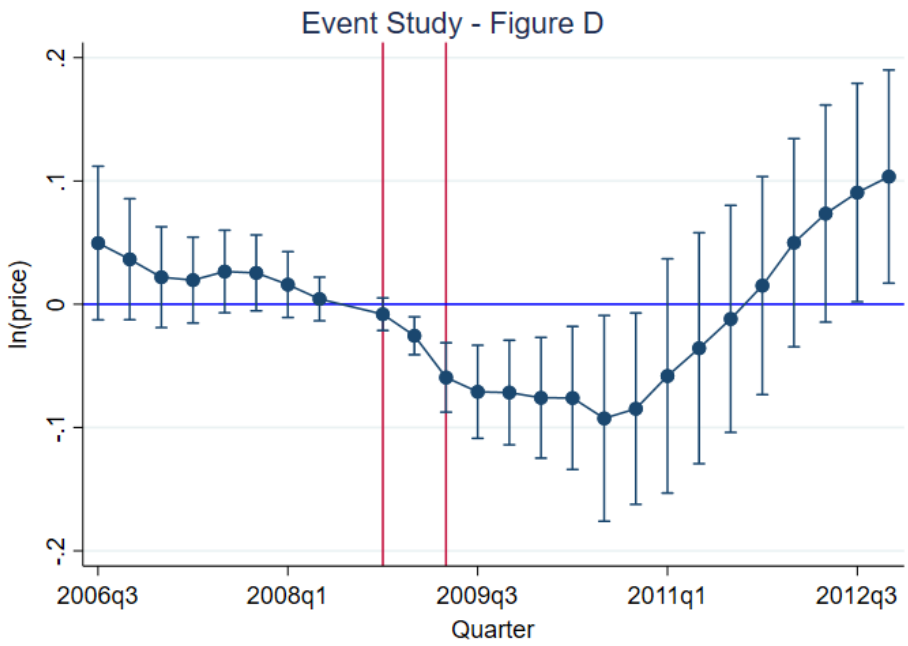


**Figure D:** Quarterly treatment effect on log prices. Confidence interval at 95% level. Normal quarter fixed effects.

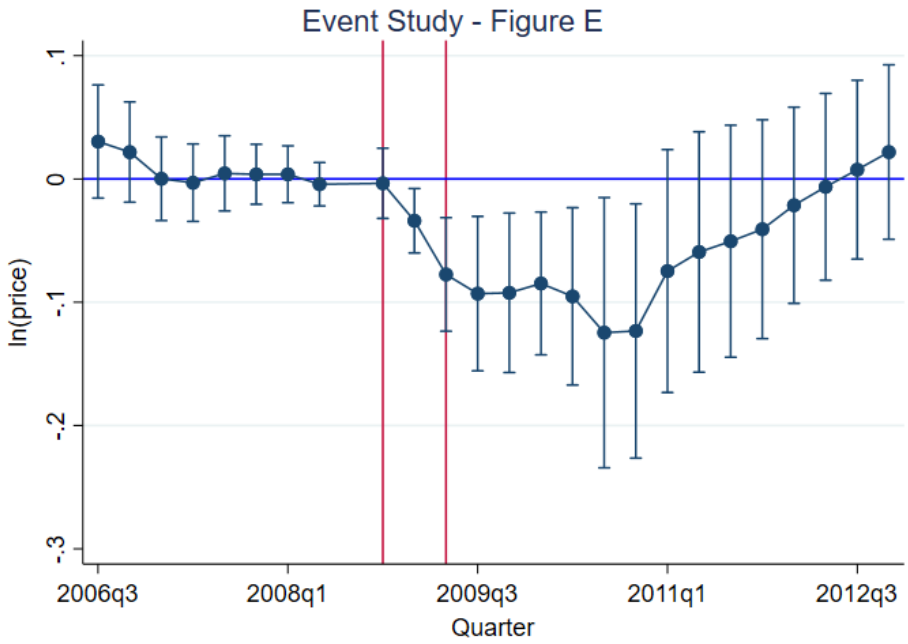


**Figure E:** Quarterly treatment effect on log prices. Confidence interval at 95% level. Flexible quarter fixed effects.